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Vitality Training - evaluation of a group learning intervention for patients with rheumatic diseases

Submission date	Recruitment status	[ ] Prospectively registered
11/07/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/10/2021	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Kare Birger Hagen

Contact details
National Resource Center for Rehabilitation in Rheumatology
Diakonhjemmet Hospital
P.B. 23
Vinderen
Oslo
Norway
0592
+47 22454855
kbh@ulrik.uio.no

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.2006.3527

Study information

Scientific Title
Vitality Training - evaluation of a group learning intervention for patients with rheumatic diseases

Acronym
VTP (Vitality Training Program)

Study objectives
Participation in the Vitality Training Program will improve psychological wellbeing, coping and health related consequences of rheumatic diseases.

Please note that details pertaining to the pilot study only will be mentioned in the relevant fields with the title 'Pilot study', and details pertaining only to the main study will be mentioned with the title 'Main study'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Pilot study: the pilot study was approved by the ethics committee on the 21st March 2001 (ref: 117-01041) with an extended approval to September 2002 (ref: 392-02-01041).
2. Main study: the National Committee for Medical Ethics in Norway approved this study on the 19th December 2006 (ref: 744-06316 1.2006.3527).

Study design
1. Pilot study: prospective one year follow-up study (2003 to 2005)
2. Main study: randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatic diseases

Interventions
Vitality Training is a ten-session program taught in groups with eight to ten participants. The whole program lasts for approximately four months with a booster session six months after the end of the program. Each session, lasting for four hours, addresses a specific theme, like: if the body could talk.., relation to self and others, what gives and take energy, anger, joy, sorrow and values and choices.

Through participation-based teaching and counseling methods patients are invited to become more aware of the relationship beween thoughts, feelings and bodily reactions, and further to explore own resources and potentials; with the emphasis on coping with current life situation. Exercises include awareness and relaxation training, guided imagery, moving to music, creative drawing, use of metaphors, free writing, sharing and listening to one other in small groups and homework.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Psychological Distress (General Health Questionnaire 20), this will be measured repeatedly five times before the intervention, five times after the intervention and five times one year after the intervention
2. Self-Efficacy (Arthritis Self-Efficacy Scale), this will be measured one time before the intervention (baseline), one time immediately after the intervention and at one year follow-up (12 months after baseline)
3. Emotional Approach Coping (Emotional Approach Coping Scale), this will be measured one time before the intervention (baseline), one time immediately after the intervention and at one year follow-up (12 months after baseline)

Secondary outcome measures
Symptoms: pain, fatigue, disease activity (Visual Analogue Score [VAS]-scales), this will be measured repeatedly five times before the intervention, five times after the intervention and five times one year after the intervention.

Additionally, patient characteristics of age, gender, civil status, work status, diagnosis, disease duration, drug use and use of health care will be collected at baseline. All data will be collected by self-reported questionnaires.

Overall study start date
30/04/2007

Completion date
31/05/2010

Eligibility

Key inclusion criteria

1. Pilot study:
1.1. Patients with rheumatic diseases
1.2. Aged 20 to 70
1.3. Minimum disease duration one year
2. Main study:
2.1. Patients with inflammatory rheumatic diseases
2.2. Age 20 to 65
2.3. Minimum disease duration one year

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
160

Total final enrolment
73

Key exclusion criteria
1. Pilot study: not speaking Norwegian language
2. Main study:
2.1. Not speaking Norwegian language
2.2. Non-inflammatory diagnosis

Date of first enrolment
30/04/2007

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
Norway

Study participating centre
National Resource Center for Rehabilitation in Rheumatology
Oslo
Norway
0592

Sponsor information

Organisation
National Resource Center for Rehabilitation in Rheumatology (Norway)

Sponsor details
Diakonhjemmet Hospital
P.B. 23
Vinderen
Oslo
Norway
0592
+47 22454840
firmapost@nrrk.diakonsyk.no

Sponsor type
Hospital/treatment centre

Website
http://www.nrrk.diakonsyk.no

ROR
https://ror.org/02jvh3a15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Resource Center for Rehabilitation in Rheumatology (Norway)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/12/2011	29/10/2021	Yes	No